Lumbar Puncture Data Management System

USER'S MANUAL

(Version 1.00, September 2011)

NACC
National Alzheimer's Coordinating Center
www.alz.washington.edu

The Lumbar Puncture Data Management System

Introduction

The Lumbar Puncture (LP) Data Management System was designed by the National Alzheimer's Coordinating Center to permit web data entry for each of the three LP Study components: **The ADC LP experience** questionnaire; **The LP requestor** questionnaire; and **The Patient LP experience**, which comprises two forms — an **initial** and a **follow-up** questionnaire. Each Center's data are secured and available only to authorized personnel at that Center. Reports may be generated by each Center and across Centers by the project PI and staff.

Requirements

The following are recommended for use of the LP Data Management System:

- Hard-wired Internet connection. A modem may be used, but can be slow and tedious.
- Minimum browser: Microsoft Explorer 8.0 or Firefox 4.0. Other browsers and versions will work, but the displays may be difficult to use.
- Minimum screen size: 17 inches. Smaller sizes will work but will be more difficult to use.

Contacts

For any type of assistance with the website or data entry, please use the contact information below:

Email: naccmail@u.washington.edu

Phone: 206-543-8637

For clinical questions related to the survey, contact John Morris, MD at morrisj@abraxas.wustl.edu.

Security

Only personnel authorized by the Centers have access to the system. Users who already have a NACC account must email NACC to let us know they would like to access the LP survey so that we can build the proper permissions into their accounts. Users who do not yet have a NACC account must request one. (For more details on setting up or modifying NACC accounts, see "Accessing the system" on page 3 of this manual.) Users have access only to their own Center's data. All data transmitted across the Internet are encrypted with at least a 128-bit encryption suite.

The forms in the survey and who should fill them out

Three separate and distinct surveys are included in the LP study database: *The ADC LP experience; The LP requestor;* and *The patient LP experience* (which is further divided into an initial and a follow-up questionnaire, the latter to be completed one week after the patient undergoes an LP). The first two surveys are brief and easy to complete, and will involve only a few persons per ADC. *The patient LP experience — initial* questionnaire will report on all subjects asked to undergo an LP during about two years of study, while *The patient LP experience — follow-up* questionnaire will be submitted only for those subjects who actually undergo an LP. A designated patient coordinator will be required, who will obtain the necessary data from subjects and medical records and complete the surveys. *The patient LP experience* part of the study is sponsored by the Alzheimer's Association and will ultimately be analyzed along with data from the Global Biomarker Consortium survey conducted outside the U.S. (Blennow et al.).

Please note that on each of the questionnaires in the study, responses may be saved and work resumed later in case of interruption.

Following is a brief description of the study components:

THE ADC LP EXPERIENCE

Number of questions	17
Who should complete	One Director-designated person per ADC, limited to the Director, Administrator, or Clinical Core Leader
When	Initially and after one year
How many should be submitted	One form per Center only

THE LP REQUESTOR

Number of questions	20
Who should complete	Any and all ADC personnel who ask subjects or patients to have an LP and are responsible for explaining the LP procedure to them
When	Initially; in the event of a new requestor; and after one year for each person completing initial survey
How many should be submitted	One for each ADC LP requestor, as described above

THE PATIENT LP EXPERIENCE ("SAFETY STUDY")

• The patient experience — initial questionnaire	
Number of questions	17
Who should complete	One designated patient coordinator (e.g., nurse, social worker, or other health professional) per site, who will interview the patient/subject (or co-participant) in person or by telephone and abstract LP procedure data from the medical record to complete the web-based questionnaire
How many should be submitted	One for each time a UDS patient is asked to undergo an LP (thus, if over time a given patient undergoes more than one LP, or additional LPs are requested, a form should be completed and submitted for each LP request). This study will continue for approximately two years and must include all such patients/subjects.
When	Form should be completed just after the patient/subject is asked to undergo an LP (for the entire two years of the study). Both subjects who decline LP and those who agree should be included.
• The patient experience — follow-up questionnaire ***(To be completed ONE WEEK after initial questionnaire)***	
Number of questions	23
Who should complete	The same designated patient coordinator who interviewed the patient/subject (or co-participant) a week earlier to complete the Initial survey will perform follow-up interviews, in person or by telephone.
How many should be submitted	One for each UDS patient who underwent an LP the previous week and was reported on in "The patient LP experience" questionnaire (ADC UDS patient ID must match). Subjects who decline LP will not have a follow-up survey.
When	Web-based form should be completed approximately ONE WEEK following the LP (for each patient during the entire two years of the study).

Please note: *The patient LP experience* study is to involve only those UDS subjects for whom LP is planned or requested as part of the ADC diagnostic workup or other research protocol; thus, no patients should be recruited to have an LP simply to provide data for this study. Also, because study data should be collected only from UDS subjects, the survey should not require any additional human studies consent beyond that normally included in ADC enrollment; however, it is always best to confer with your institution's IRB. Of course, the consent for the LP procedure itself is a separate issue.

Detailed operation of the lumbar puncture data management system

ACCESSING THE SYSTEM

The system is accessed through the NACC website. Before using this system, you must contact NACC at naccmail@uw.edu to let us know you need access to the LP Data Management System.

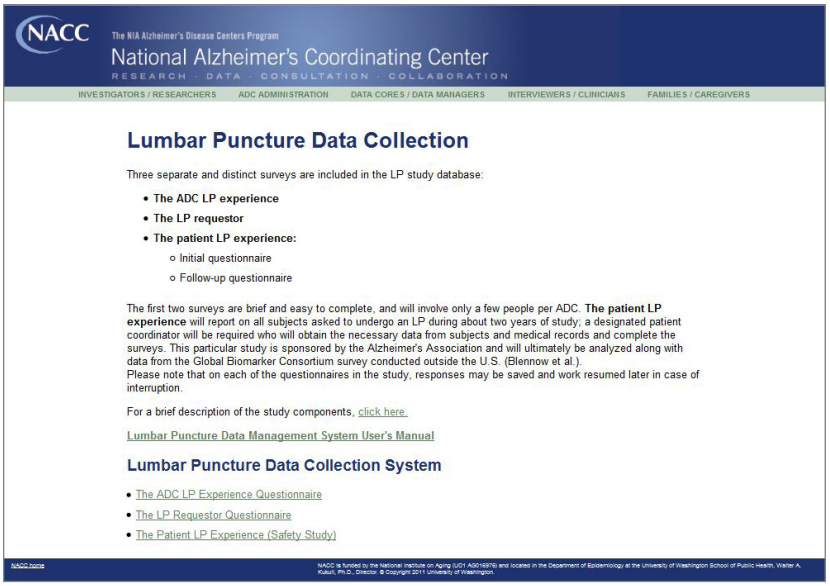
In your email, please tell us:

- Your name
- The name of your Center
- Your ADC role (e.g., Director, Administrator, Clinical Core Leader)
- What function you will perform in the study (person designated by Director to submit ADC LP Experience form, LP requestor, or designated patient coordinator)

If NACC determines that you are authorized to access this area of the website:

- If you already have a NACC account, we will modify the permissions on that account to give you access to the LP Data Management System.
- If you do not already have a NACC account, we will ask you to choose a user name and password so that we can create one for you.

You may then access the system by going to the entrance portal at:
https://www.alz.washington.edu/LP/lpdata.html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Lumbar Puncture Data Collection
Three separate and distinct surveys are included in the LP study database:
The ADC LP experience
The LP requestor
The patient LP experience:
Initial questionnaire
Follow-up questionnaire
The first two surveys are brief and easy to complete, and will involve only a few people per ADC. The patient LP experience will report on all subjects asked to undergo an LP during about two years of study; a designated patient coordinator will be required who will obtain the necessary data from subjects and medical records and complete the surveys. This particular study is sponsored by the Alzheimer's Association and will ultimately be analyzed along with data from the Global Biomarker Consortium survey conducted outside the U.S. (Blennow et al.).
Please note that on each of the questionnaires in the study, responses may be saved and work resumed later in case of interruption.
For a brief description of the study components, click here.
Lumbar Puncture Data Management System User's Manual
Lumbar Puncture Data Collection System
The ADC LP Experience Questionnaire
The LP Requestor Questionnaire
The Patient LP Experience (Safety Study)
NACC home
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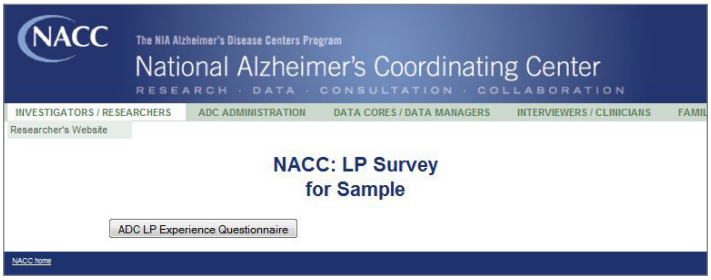
Entrance portal to the Lumbar Puncture Data Management System

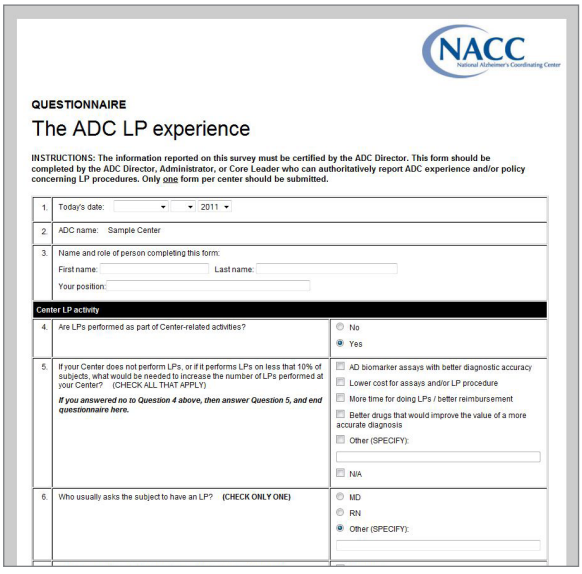
THE ADC LP EXPERIENCE QUESTIONNAIRE

Clicking the link to *The ADC LP experience* questionnaire will bring you to the following page. Click your Center's name. You can access only the Center for which you are authorized.

After you click on your Center name, you will be taken to the following page for your Center:



When you click this link, you will be taken to the electronic form, where you can enter data and save it to be completed later or submit it when it is complete.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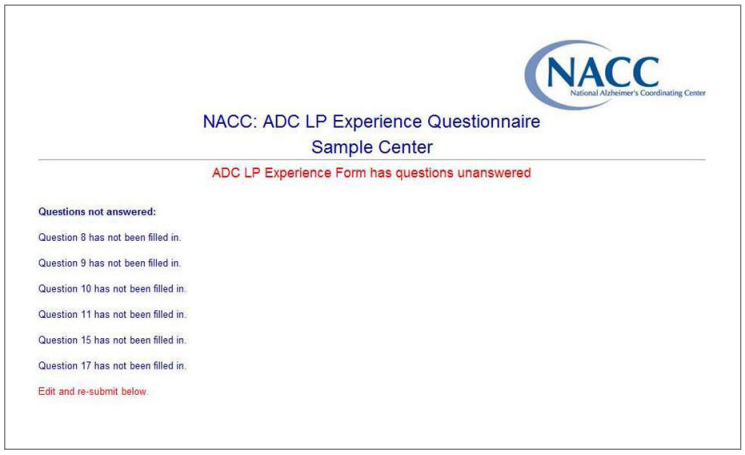
QUESTIONNAIRE
The ADC LP experience
INSTRUCTIONS: The information reported on this survey must be certified by the ADC Director. This form should be completed by the ADC Director, Administrator, or Core Leader who can authoritatively report ADC experience and/or policy concerning LP procedures. Only one form per center should be submitted.
1. Today's date: 2011
2. ADC name: Sample Center
3. Name and role of person completing this form:
First name: Last name:
Your position:
Center LP activity
4. Are LPs performed as part of Center-related activities?
No
Yes
5. If your Center does not perform LPs, or if it performs LPs on less that 10% of subjects, what would be needed to increase the number of LPs performed at your Center? (CHECK ALL THAT APPLY)
If you answered no to Question 4 above, then answer Question 5, and end questionnaire here.
AD biomarker assays with better diagnostic accuracy
Lower cost for assays and/or LP procedure
More time for doing LPs / better reimbursement
Better drugs that would improve the value of a more accurate diagnosis
Other (SPECIFY):
N/A
6. Who usually asks the subject to have an LP? (CHECK ONLY ONE)
MD
RN
Other (SPECIFY):

Once you have submitted the form, automated error checking will begin to ensure that all items have been completed. If the form is not complete, you will get an error message like the one below. At this point, you should supply the missing response(s) and resubmit the form.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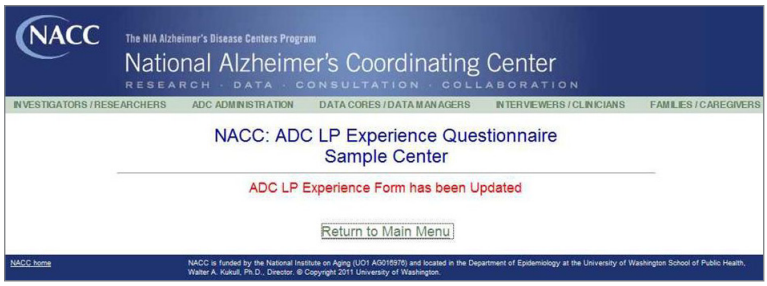
National Alzheimer's Coordinating Center
NACC: ADC LP Experience Questionnaire
Sample Center
ADC LP Experience Form has questions unanswered
Questions not answered:
Question 8 has not been filled in.
Question 9 has not been filled in.
Question 10 has not been filled in.
Question 11 has not been filled in.
Question 15 has not been filled in.
Question 17 has not been filled in.
Edit and re-submit below.

Once the form is submitted and complete, the following page will be displayed: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NACC: ADC LP Experience Questionnaire
Sample Center
ADC LP Experience Form has been Updated
Return to Main Menu
NACC home
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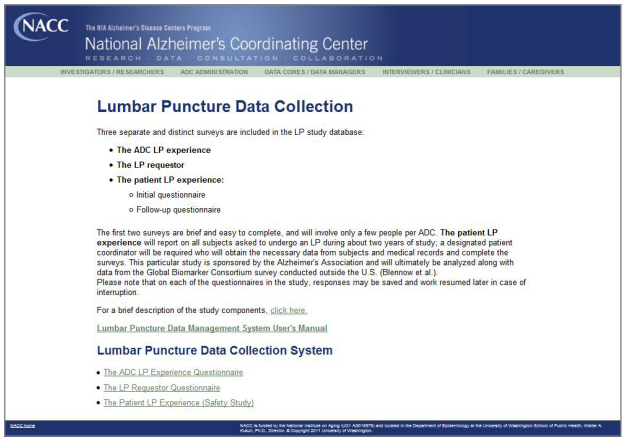
To enter data for the next form, go back to the Lumbar Puncture Data Collection entrance portal: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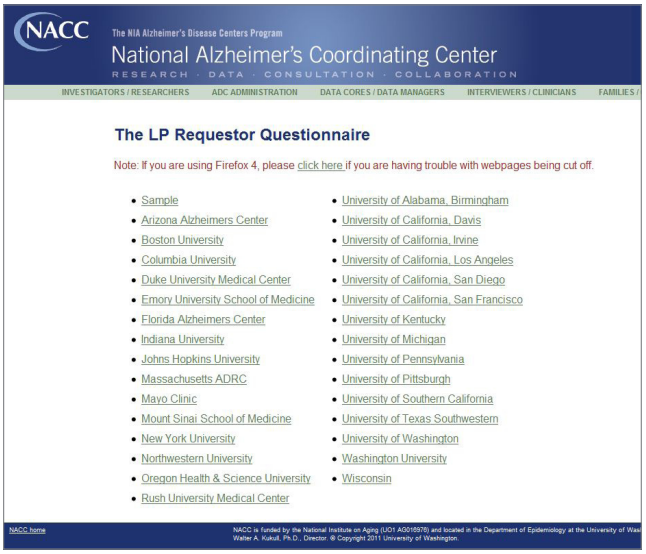
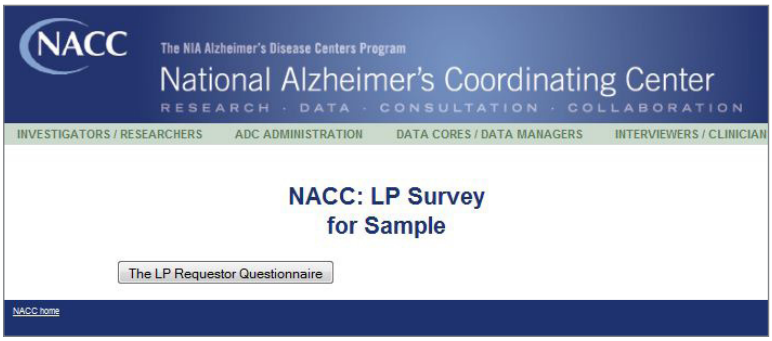
Please note that on each of the questionnaires in the study, responses may be saved and work resumed later in case of interruption.
For a brief description of the study components, click here.
Lumbar Puncture Data Management System User's Manual
Lumbar Puncture Data Collection System
The ADC LP Experience Questionnaire
The LP Requestor Questionnaire
The Patient LP Experience (Safety Study)
NACC home

THE LP REQUESTOR QUESTIONNAIRE

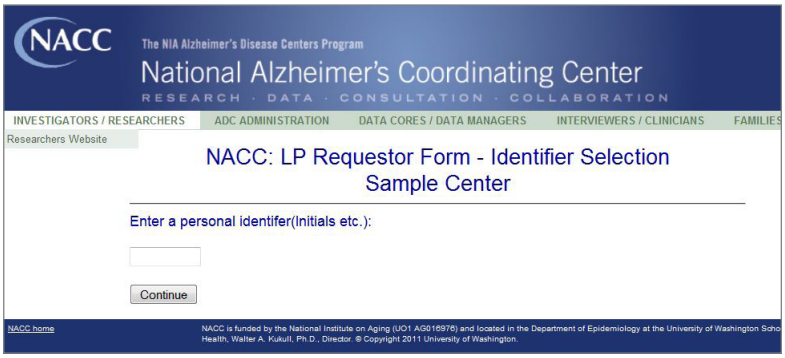
Clicking the link to *The LP requestor* questionnaire will bring you to the following page. Click your Center's name. You can access only the Center for which you are authorized.



After you click your Center name, you will be taken to the following page for your Center:



When you click this link, you will be directed to the following page, where you will need to enter a personal identifier. Choose a simple identifier — one you can remember easily in case you need to go back and modify or complete the form.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Researchers Website
NACC: LP Requestor Form - Identifier Selection
Sample Center
Enter a personal identifer(Initials etc.):
Continue
NACC home
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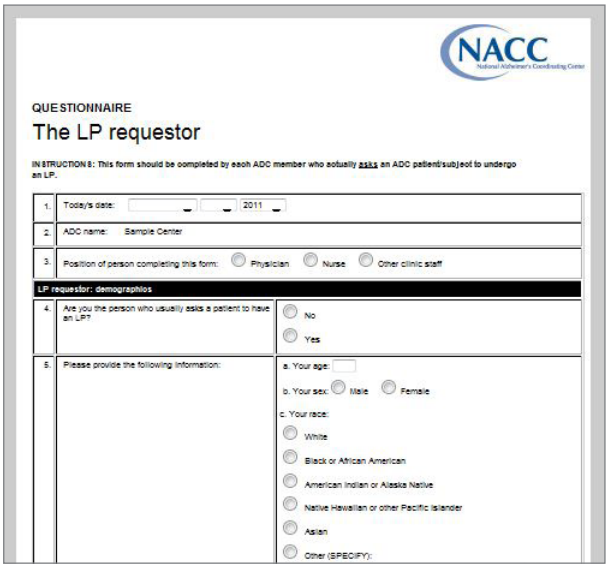
After you enter your personal identifier, click Continue to go to the electronic form, where you can enter data. You can enter data and save it to resume later or submit it when completed.



QUESTIONNAIRE

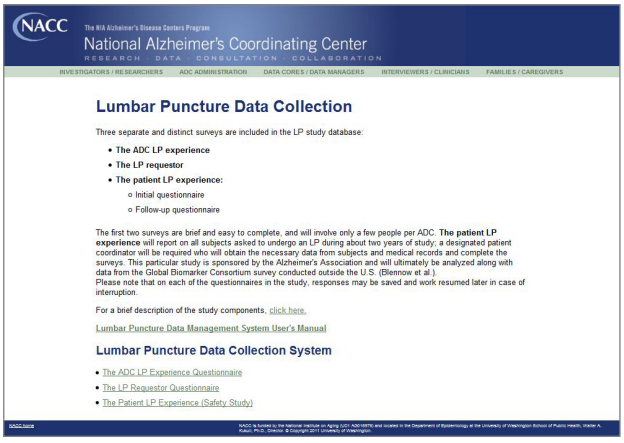
The LP requestor

INSTRUCTIONS: This form should be completed by each ADC member who actually asks an ADC patient/subject to undergo an LP.

1.	Today's date:	2011
2.	ADC name: Sample Center	
3.	Position of person completing this form:	Physician Nurse Other clinic staff
LP requestor: demographics		
4.	Are you the person who usually asks a patient to have an LP?	No Yes
5.	Please provide the following information:	a. Your age: b. Your sex: Male Female c. Your race: White Black or African American American Indian or Alaska Native Native Hawaiian or other Pacific Islander Asian Other (SPECIFY):

Once you have submitted the form, automated error checking will begin to ensure that all items have been completed. If any errors are found, modify the form and resubmit it.

To enter data for the next form, go back to the Lumbar Puncture Data Collection entrance portal:



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National Alzheimer's Coordinating Center

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Lumbar Puncture Data Collection

Three separate and distinct surveys are included in the LP study database:

- **The ADC LP experience**
- **The LP requestor**
- **The patient LP experience:**
  - Initial questionnaire
  - Follow-up questionnaire

The first two surveys are brief and easy to complete, and will involve only a few people per ADC. **The patient LP experience** will report on all subjects asked to undergo an LP during about two years of study; a designated patient coordinator will be required who will obtain the necessary data from subjects and medical records and complete the surveys. This particular study is sponsored by the Alzheimer's Association and will ultimately be analyzed along with data from the Global Biomarker Consortium survey conducted outside the U.S. (Blennow et al.).
Please note that on each of the questionnaires in the study, responses may be saved and work resumed later in case of interruption.

For a brief description of the study components, click here.

Lumbar Puncture Data Management System User's Manual

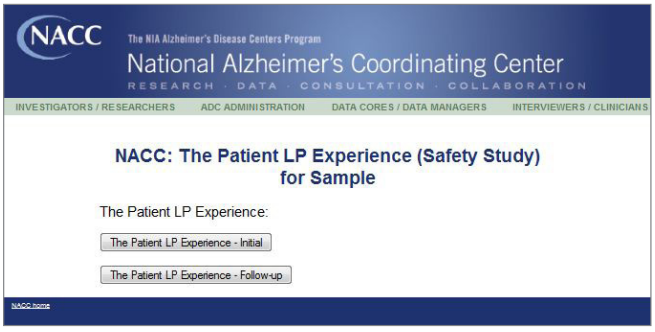
Lumbar Puncture Data Collection System

- The ADC LP Experience Questionnaire
- The LP Requestor Questionnaire
- The Patient LP Experience (Safety Study)

THE PATIENT LP EXPERIENCE (SAFETY STUDY)

Clicking the link to *The patient LP experience* (Safety Study) will bring you to the following page. Click your Center's name. You can access only the Center for which you are authorized.

After you click your Center name, you will be taken to the following page for your Center: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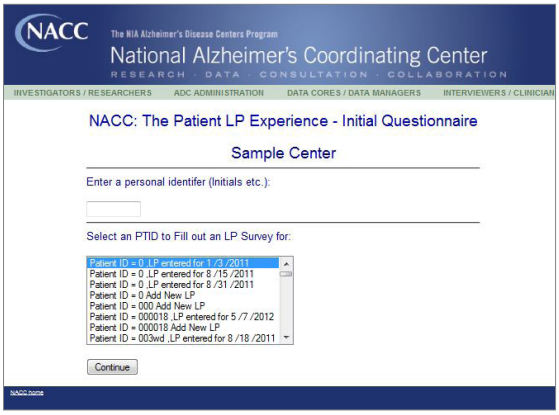
NACC: The Patient LP Experience (Safety Study)
for Sample
The Patient LP Experience:
The Patient LP Experience - Initial
The Patient LP Experience - Follow-up
NACC home

To enter data for *The patient LP experience — initial* questionnaire, click the appropriate link, and the following page will be displayed: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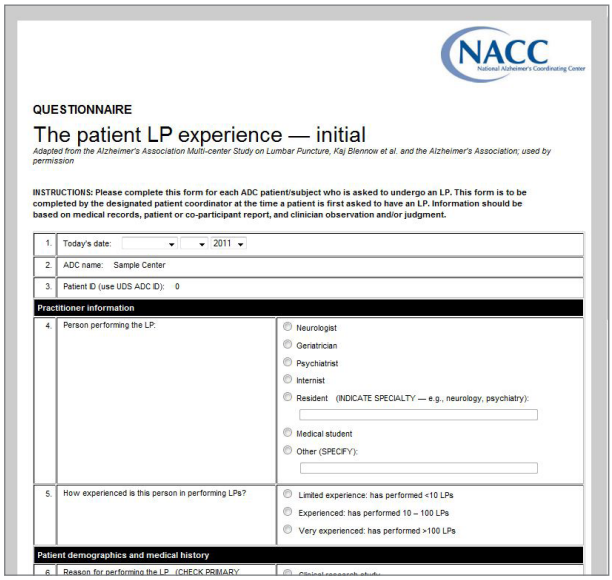
NACC: The Patient LP Experience - Initial Questionnaire
Sample Center
Enter a personal identifer (Initials etc.):
Select an PTID to Fill out an LP Survey for:
Patient ID = 0 ,LP entered for 1 /3 /2011
Patient ID = 0 ,LP entered for 8 /15 /2011
Patient ID = 0 ,LP entered for 8 /31 /2011
Patient ID = 0 Add New LP
Patient ID = 000 Add New LP
Patient ID = 000018 ,LP entered for 5 /7 /2012
Patient ID = 000018 Add New LP
Patient ID = 003wd ,LP entered for 8 /18 /2011
Continue
NACC home

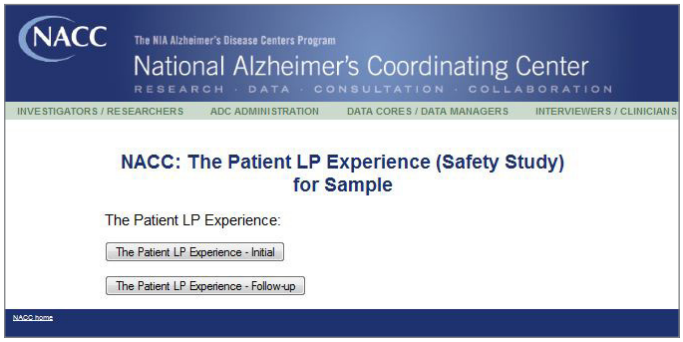
Enter a personal identifier — one you can remember easily in case you need to go back and modify or complete the form. **You also must use the same identifier when you complete *The patient experience — follow-up* form during the following week.**

Choose the NACC ID of the patient whose form you are entering and click Continue to go to the electronic form, where you can enter data and save it to resume later or submit it when completed.


NACC
QUESTIONNAIRE
The patient LP experience — initial
Adapted from the Alzheimer's Association Multi-center Study on Lumbar Puncture, Kaj Blennow et al. and the Alzheimer's Association; used by permission
INSTRUCTIONS: Please complete this form for each ADC patient/subject who is asked to undergo an LP. This form is to be completed by the designated patient coordinator at the time a patient is first asked to have an LP. Information should be based on medical records, patient or co-participant report, and clinician observation and/or judgment.
1. Today's date: 2011
2. ADC name: Sample Center
3. Patient ID (use UDS ADC ID): 0
Practitioner information
4. Person performing the LP:
Neurologist
Geriatrician
Psychiatrist
Internist
Resident (INDICATE SPECIALTY — e.g., neurology, psychiatry):
Medical student
Other (SPECIFY):
5. How experienced is this person in performing LPs?
Limited experience: has performed <10 LPs
Experienced: has performed 10 – 100 LPs
Very experienced: has performed >100 LPs
Patient demographics and medical history

Once you have submitted the form, automated error checking will begin to ensure that all items have been completed. If any errors are found, modify the form and resubmit.

To enter the follow-up data, which are collected one week after the LP is performed, go to the follow-up form under *The patient LP experience* (Safety Study) tab: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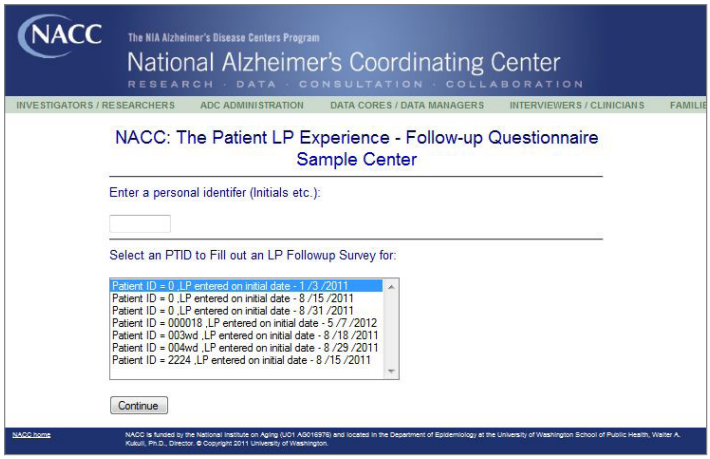
NACC: The Patient LP Experience (Safety Study)
for Sample
The Patient LP Experience:
The Patient LP Experience - Initial
The Patient LP Experience - Follow-up
NACC home

To enter data for *The patient LP experience — Follow-up* form, click the appropriate link, and the following page will be displayed: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NACC: The Patient LP Experience - Follow-up Questionnaire
Sample Center
Enter a personal identifer (Initials etc.):
Select an PTID to Fill out an LP Followup Survey for:
Patient ID = 0 ,LP entered on initial date - 1 /3 /2011
Patient ID = 0 ,LP entered on initial date - 8 /15 /2011
Patient ID = 0 ,LP entered on initial date - 8 /31 /2011
Patient ID = 000018 ,LP entered on initial date - 5 /7 /2012
Patient ID = 003wd ,LP entered on initial date - 8 /18 /2011
Patient ID = 004wd ,LP entered on initial date - 8 /29 /2011
Patient ID = 2224 ,LP entered on initial date - 8 /15 /2011
Continue
NACC home
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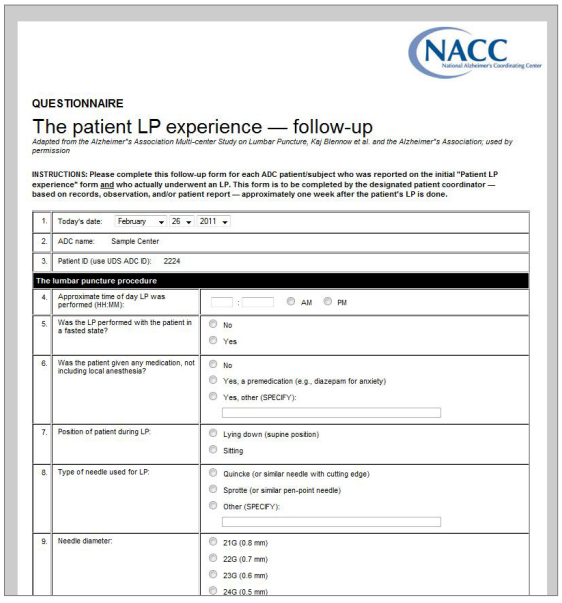
Enter the same personal identifier that you used when entering the initial patient experience form.

Choose the NACC ID of the patient whose form you are submitting, and click Continue to go to the electronic form, where you can enter data and save it to resume later or submit it when it is completed.


NACC
QUESTIONNAIRE
The patient LP experience — follow-up
Adapted from the Alzheimer's Association Multi-center Study on Lumbar Puncture, Kaj Blennow et al. and the Alzheimer's Association; used by permission
INSTRUCTIONS: Please complete this follow-up form for each ADC patient/subject who was reported on the initial "Patient LP experience" form and who actually underwent an LP. This form is to be completed by the designated patient coordinator — based on records, observation, and/or patient report — approximately one week after the patient's LP is done.
1. Today's date: February 26 2011
2. ADC name: Sample Center
3. Patient ID (use UDS ADC ID): 2224
The lumbar puncture procedure
4. Approximate time of day LP was performed (HH:MM): AM PM
5. Was the LP performed with the patient in a fasted state? No Yes
6. Was the patient given any medication, not including local anesthesia? No Yes, a premedication (e.g., diazepam for anxiety) Yes, other (SPECIFY):
7. Position of patient during LP: Lying down (supine position) Sitting
8. Type of needle used for LP: Quincke (or similar needle with cutting edge) Sprotte (or similar pen-point needle) Other (SPECIFY):
9. Needle diameter: 21G (0.8 mm) 22G (0.7 mm) 23G (0.6 mm) 24G (0.5 mm)

Once you have submitted the form, automated error checking will begin to ensure that all items have been completed. If any errors are found, modify the form and resubmit it.